Dietary Supplement Use Among Breast and Prostate Cancer Patients Undergoing Radiation Therapy

A Senior Honors Thesis

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I. Abstract

Background: As more Americans attempt to take charge of their health, interest in and usage of nutritional supplements has increased among the general population, and even more among cancer patients. However, few studies have accurately measured supplement use among this population. There is little scientific evidence that supplements will reduce the side effects of cancer therapy or directly treat the cancer. In addition, controversy surrounding antioxidants and their effect on cancers treated with radiation therapy raises many questions regarding their safety and efficacy.

Objective: To define the nutritional supplement use among women and men undergoing radiation therapy for breast and prostate cancers, including amount, frequency, and type of supplement use as well the relationship between supplement use and quality of life.

Design: Fifty-six women and fifty-two men with newly diagnosed breast and prostate cancers who chose radiation treatment completed an interview regarding their supplement use and completed demographic and quality of life questionnaires prior to the initiation of radiation therapy, at completion of radiation therapy, and at follow-up six weeks later. Supplement ingredients and amounts consumed were quantified, and demographic and quality of life data was entered into Excel databases.

Results: The mean age was 53 years for breast cancer patients and 63 years for prostate cancer patients. At the initiation of radiation therapy, 73% (n=41) of women and 63% (n=33) of men reported supplement use. A total of 133 different supplement products were consumed among women and 113 among men. Among supplement users, an average of 3.2 supplements per woman and 3.4 supplements per man was consumed. The most common supplement consumed in both sexes was a combination multivitamin/multimineral (52% of women, 44% of men). Antioxidants were also prevalent, with 46% of men and women consuming supplements containing antioxidant nutrients at the initiation of therapy, excluding those in multivitamin products. For breast cancer patients, indicators of quality of life such as global health status increased from initiation of radiation therapy to follow-up six weeks following therapy completion, while indicators of physical and functioning and fatigue did not significantly change. In the prostate cancer cohort, physical functioning and vitality markers steadily decreased throughout the enrollment period, while markers of general health were varied. The relationship of supplement use to quality of life indicators is currently under investigation.

Significance: This study is one of the most detailed and accurate assessments of supplement use among cancer patients undergoing radiation therapy. Our findings suggest that supplement use among women and men newly diagnosed with breast and prostate cancers is more common than previously reported for cancer patients, and significantly higher than the general population. Defining dietary supplement use of these cohorts will help us design randomized clinical trials to investigate the effects of supplements on cancer treatment with radiation therapy.

II. Introduction

As more Americans attempt to take charge of their health, interest in and usage of nutritional supplements has increased among the general population. Recent cross-sectional studies including the Third National Health and Nutrition Examination Survey (NHANES III) estimate that approximately 52% of the U.S. population takes a vitamin, mineral, or other dietary supplement (CDC). The prevalence of nutritional supplement use among patients with a history of cancer has been reported to be even higher (Miller, et al. 2008). Accurate quantification of nutritional supplement use is very difficult. Many patients do not report use of supplements to their medical caregivers and reviewing a medical chart notoriously underestimates supplement use. A study by Hensrud et al. in 1999 found that only 30.5% of patients reported supplement use during a routine physical exam on their medical forms. Additionally, studies which rely on self-report are frequently inaccurate as patients often cannot recall the type of supplement taken and rarely can provide information regarding the dose of supplement components. Although information marketed towards consumers advertises the health benefits of supplements, little is known about their bioavailability, mechanisms of action within the body, interactions with one another, and overall safety and efficacy.

One area of particular controversy concerns the role of supplements, particularly those in the category called “antioxidants”, during radiation therapy for cancer. It is well known that ionizing radiation induces free-radical formation and that this is one mechanism mediating the therapeutic action of radiotherapy. Thus, two opposing hypotheses have emerged. One proposes that increased antioxidant supplementation will prevent the side-effects of radiation. The opposing hypothesis suggests that increasing antioxidant supplements in a cancer will reduce the ability of radiation to treat the cancer. These opposing concepts have not been adequately tested in humans and evidence based guidance for those undergoing radiotherapy is essentially nonexistent.

Our long-term goal is to address this issue. In order to proceed with future studies in this field it will first be necessary to accurately document the current prevalence of supplement use, the types of supplements consumed, and the doses of various components consumed during cancer radiotherapy for specific cancer types. Accurately quantifying nutritional supplement use among cancer patients is essential to beginning to understand the effects of supplements on radiation therapy.

Supplement Usage in the General Population:

Nutritional supplement use among the general population has been consistently increasing. The Slone Survey conducted by Kaufman et al., in the late 1990's found that 40% of the 2590 participants had reported taking a vitamin or mineral in the preceding week, and 14% reported taking at least one herbal supplement. Percentages can be assumed to be even higher with the advent of the 21st century, as evidenced by a national survey indicating an increase in use of complementary and alternative medicine from 43% in 1997 to 62% in 2002 (Bardia et al. 2007). It is clear, however, that many consumers are unaware of the effects and safety of many of these supplements. Greger (2001) states that consumers are beginning to take charge of their health, but that characteristics of supplement use predict less than 30% of diet-related behaviors. This is important because it implies that consumers may be taking nutritional supplements while being unaware of their diets. In addition, traditional medicine practitioners often lack information on supplements, and it is difficult to determine which agencies are most qualified to disseminate information to the public (Greger, 2001).

It is interesting to note the reasons consumers take nutritional supplements, and even more surprising to find that some do not take certain supplements for their evidence-based indications. In a study conducted by the 2002 National Health Interview Survey, only 55% of participants used herbal supplements consistent with their indications (Bardia et al. 2007). It is

therefore important to understand the need to educate supplement users about the indications and contraindications for specific vitamins, minerals, and herbal supplements. Some general reasons that consumers have stated for taking vitamins and minerals are for general health, or as a supplement to the diet, while herbal medications are consumed most commonly for general health, arthritis, and memory improvement (Kaufman et al. 2002). However, several other factors can determine the use, frequency and duration of supplement use.

Many studies and surveys have illustrated characteristics of consumers that are more likely to take nutritional supplements. In general, supplement users are frequently older, Caucasian, and females (Greger, 2001). In addition, those consumers who are educated beyond high school or have a higher income are more apt to take supplements than those less educated or less wealthy. Positive lifestyle factors such as abstinence from smoking and excessive alcohol intake, as well as those who exercise regularly, further prove to be indicators of supplement use (Greger, 2001). A mailed questionnaire study from 2000-2002 reported that persons who ate a low fat diet, consumed more fruits and vegetables, and were screened for cancer were more likely to take herbal or specialty supplements (Gunther, et al. 2004). In general, trends show that consumers who are more educated, have a higher socioeconomic status, are concerned about their health, diet, and physical well-being are more likely to use supplements.

Supplement Usage among Cancer Patients:

Recent studies have reported not only an increase in supplement use among the general population, but also among cancer patients. In 2001, the California Health Interview Survey found that supplement use was higher among participants that reported a history of cancer, a noncancer chronic condition, or both (Miller et al. 2008). Interestingly, four of the seven commonly consumed vitamins were antioxidants, which have received increased

attention for cancer prevention. Another study from a colorectal chemoprevention trial found that 55% of patients with a history of colorectal carcinoma used an average of 2.6 supplements each (Sandler, et al. 2001). It is important to consider not only whether this cohort is taking supplements in general but also how many are consumed simultaneously.

The term complementary and alternative medicine (or CAM) is often used interchangeably with the term nutrient supplement. However, CAM, as defined by the National Institutes of Health, encompasses much more than simply nutritional supplements. CAM can include diet, mind-body techniques, folk remedies, manual healing methods, and vitamin, mineral, and herbal treatments (Bernstein, 2001). Cancer patients and proponents claim that various CAM treatments may help to eliminate the side effects of chemotherapy (Bernstein, 2001). Some patients even abandon evidence-based therapies in favor of untested CAM cancer treatments.

Although supplement use is common among cancer patients and survivors, it has been reported that adults diagnosed with cancer may also make additional lifestyle changes in diet and physical activity. A cancer diagnosis often may cause psychological distress that motivates the individual to begin health promoting activities and to reduce risk (Patterson et al. 2003). In addition, cancer patients that feel a greater sense of personal control will be more motivated to change their lifestyle, and therefore may be more likely to take nutritional supplements. A population-based telephone survey of breast, prostate, and colorectal patients revealed that two thirds of patients made at least one behavior change in the year after their cancer diagnosis, and that 50% started taking new dietary supplements (Patterson et al. 2003). This data raises the significant question of whether supplements are used by cancer patients as a coping mechanism or as an actual health improvement strategy.

Federal Regulation of the Dietary Supplement Industry:

The 1994 Dietary Supplement, Health and Education Act (DSHEA) significantly changed the way supplements were regulated in the United States. Prior to its passage, the Food and Drug Administration regarded dietary supplements as foods, and all ingredients were subject to safety evaluation. However, the passage of DSHEA meant that manufacturing, marketing, and the health claims of supplements were no longer monitored and regulated based upon scientific rigor and that consumers could no longer assume safety, purity or efficacy. In other words, products were assumed to be safe unless the Food and Drug Administration could prove otherwise (JAMA, 2002). In addition, Congress expanded the definition of a dietary supplement to include not only essential nutrients such as vitamins, minerals, and proteins, but also fish oils, garlic, enzymes, and other forms of supplementation (FDA, 1995). Many cancer patients consume supplements with the belief that these supplements will reduce the side effects of cancer therapy, directly treat the cancer, or reduce the risk of cancer recurrence. However, there is very little scientific evidence to support these claims. Indeed, it is possible that some commonly consumed dietary supplements may actually be harmful to cancer patients. Thus, cancer patients are often unable to obtain scientifically-supported guidance to help them make informed decisions about the use of nutritional supplements.

Interactions between Nutrient Supplements and Radiation Therapy:

One of the most controversial issues regarding supplement usage in cancer patients is the use of antioxidants while undergoing radiation therapy. While antioxidants may decrease oxidative stress and potentially play a role in aging and disease prevention, there are also studies which claim they may interfere with the body's defense mechanisms that rid the body of damaged cells, such as those involved in cancer development. Radiation therapy as a

treatment for cancer involves direct ionization of DNA and produces free radicals in the tissue, with the ultimate goal of increasing DNA damage in tumor cells and altering cell homeostasis to increase apoptosis of cancerous cells (Bjelakovic, 2007). Conversely, antioxidants counteract free radicals, prevent tissue damage, and repair cell membranes by affecting processes such as cell proliferation, apoptosis, and angiogenesis (Lawenda et al. 2008). Furthermore, the bioavailability and mechanisms of action of antioxidants are unknown and often synthetic and factory-processed forms cannot be proven safe. It is clear that these two processes are in direct conflict with each other and that use of antioxidants during radiation therapy must be more carefully researched.

Despite concern over this issue, there are still arguments for the use of antioxidants during radiotherapy. Many claim that antioxidant supplementation can enhance the benefits of treatment by inhibiting the growth of tumor cells. Some argue that use of antioxidants may also alleviate side effects of conventional therapies by reducing toxicities, as well as improving general health and well-being (Ladas et al. 2004). Conversely, those who discourage antioxidant supplementation during radiotherapy believe it will interfere with the efficacy of treatment by scavenging the free radicals produced by the radiation and by repairing damage to the tumor cells the radiation is attempting to destroy. A study by Bairati is the most important randomized clinical trial to date involving use of antioxidant vitamins in head and neck cancer patients. Results found that the severity of negative side effects of radiation was reduced, but that overall improvement in quality of life was unchanged with antioxidant supplementation (Bairati et al. 2005). In addition, results illustrated that the antioxidants actually caused adverse effects, especially when a-tocopherol and b-carotene were administered together, and that the rate of local recurrence of the cancer was 56% higher among the supplemented patients than in the placebo group (Bairati et al. 2005). This study and others confirm the need for greater research into trends of antioxidant usage among cancer patients and effects of supplementation on the effectiveness of conventional cancer treatments.

The objective of this study is therefore to define the nutritional supplement use among women and men undergoing radiation therapy for breast and prostate cancers, including amount, frequency, and type of supplement use as well the relationship between supplement use and quality of life.

III. Subjects and Methods:

Design: Each enrolled subject was interviewed prior to their first radiation therapy treatment for cancer. The visit consisted of screening the subject for eligibility, obtaining consent, and describing the study. Enrolled subjects were given demographic and quality of life questionnaires to complete and return to their next appointment, and were instructed to bring containers and labels of all consumed supplements. Information regarding type of supplement, duration of use, and frequency of use was carefully recorded. Subjects were seen again at the completion of radiation therapy and at the follow-up visit six weeks later in which they were administered the same demographic and quality of life questionnaires and noted any differences in supplement consumption from the initiation of radiation therapy (Figure 1).

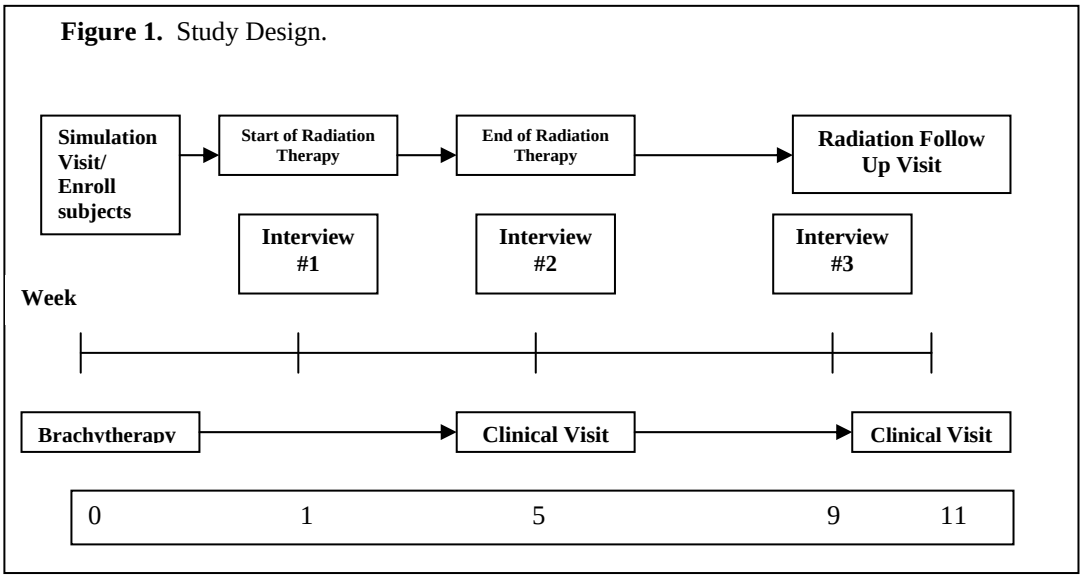


Figure 1. Study Design.

Recruitment: Patients were recruited from a pool of prostate and breast cancer patients enrolled at the James Cancer Hospital and Solove Research Institute. Men had chosen external beam irradiation or brachytherapy as treatment for their prostate cancer, and women had chosen external beam irradiation for their breast cancer. There were no age restrictions for the study, but subjects who could not independently consent to participation were not included. Patients with metastatic cancer were not enrolled. Fifty-six women and fifty-two men were recruited to the study and most completed the three time point interview process.

Data procurement and management: Supplement containers were examined and dosing was discussed with each patient to document frequency, duration, and amount of product consumed. Labels were photocopied and components of supplements were entered into an Excel database. When necessary, content of supplements was verified using company websites. Data was also procured through a questionnaire incorporating demographics and a second questionnaire which assessed quality of life. A file for each patient was created and included consent forms, all completed questionnaires, and all photocopied supplement labels.

IV. Statistics:

Demographic data, quality of life data, and supplement use data were entered into three different Excel databases and analyzed using descriptive analysis. Milligram and microgram amounts of each nutrient were calculated and all information was stored in a separate Excel database. Descriptive statistics were used to determine demographic characteristics, changes in quality of life markers from initiation of radiation therapy to follow up, and possible relationships between supplement use and quality of life. In addition, Excel was used to create graphs illustrating number of supplements consumed among supplement users as well as categories of dietary supplements consumed.

V. Results:

Demographic Data:

Refer to Appendix A for the brief demographic questionnaire each patient was asked to complete. As indicated in Table 1, fifty-six breast cancer patients were enrolled in the study, with a mean age of 53 years and mean of 4.7 months since diagnosis. The mean body mass index (BMI) was 27.2. The majority of women were Caucasian (80%), on paid employment status (70%), and married (63%). Seventy-three percent of women completed college or graduate school. Alcohol use was prominent among the cohort, with 55% of women reporting alcohol consumption, while only 11% reported smoking.

Demographic characteristics for prostate cancer patients are shown in Table 2. Fifty-two prostate cancer patients participated in the study with a mean age of 63 years and mean of 4.0 months since diagnosis. The mean body mass index (BMI) of the men was 28.2. A majority of the men were Caucasian (79%) and married (86%). Education level and employment status was relatively spread out, with 39% of men finishing high school, 29% finishing college, 50% retired, and 41% on paid employment status. Alcohol use was more prominent among men than cigarette smoking, with 52% reporting alcohol use and 10% reporting smoking.

Quality of Life Data:

To assess markers of quality of life among the cohort of breast cancer patients, this study used the 53-item EORTC Quality of Life Questionnaire-C30 and the EORTC QLQ-BR23 breast cancer supplementary module (Appendix B). Three scales were used to assess quality of life at initiation of radiation therapy, at completion of therapy, and at follow-up six weeks later.

Table 1. Demographic characteristics, breast cancer patients.

	Mean (±SD)
Age (years)	52.7 (±10.6)
Height (inches)	64.6 (±2.8)
Weight (pounds)	164.2 (±41.3)
BMI (kg/m^2)	27.2 (±7.6)
Months since Dx	4.7 (±2.4)

	N (%)
Race: (n=56)	
Caucasian	45 (80.4)
African American	10 (17.9)
Hispanic	0 (0.0)
Other	1 (1.8)
Education: (n=54)	
Some High School	2 (3.6)
High School	11 (19.6)
College	24 (42.9)
Graduate School	17 (30.4)
Employment: (n=55)	
Paid	39 (70.0)
Retired	3 (5.4)
Unemployed	7 (12.5)
Other	6 (10.7)
Income: (n=51)	
<$20,000	6 (10.7)
$20,000-$39,999	16 (28.6)
$40,000-$59,999	10 (17.9)
$60,000-$99,999	11 (19.6)
>$100,000	8 (14.3)
Marital Status: (n=55)	
Single	7 (12.5)
Married	35 (62.5)
Widowed	3 (5.4)
Divorced/Separated	10 (17.9)
Smoking: (n=55)	
Smoker	6 (10.7)
Nonsmoker	49 (87.5)
Alcohol Use: (n=54)	
Yes	31 (55.4)
No	23 (41.1)

Table 2. Demographic characteristics, prostate cancer patients.

	Mean (±SD)
Age (years)	62.8 (±7.7)
Height (inches)	70.4 (±2.9)
Weight (pounds)	198.4 (±32.7)
BMI (kg/m^2)	28.2 (±4.4)
Months since Dx	4.0 (±4.3)

	N (%)
Race: (n=52)	
Caucasian	41 (78.9)
African American	8 (15.4)
Hispanic	0 (0.0)
Other	3 (5.8)
Education: (n=52)	
Some High School	6 (11.5)
High School	20 (38.5)
College	15 (28.9)
Graduate School	11 (21.2)
Employment: (n=51)	
Paid	21 (41.2)
Retired	26 (50.0)
Unemployed	1 (2.0)
Other	3 (5.9)
Income: (n=44)	
<$20,000	7 (15.9)
$20,000-$39,999	12 (27.3)
$40,000-$59,999	12 (27.3)
$60,000-$99,999	6 (13.6)
>$100,000	7 (15.9)
Marital Status: (n=51)	
Single	3 (5.9)
Married	44 (86.3)
Widowed	0 (0.0)
Divorced/Separated	4 (7.8)
Smoking: (n=52)	
Smoker	5 (9.6)
Nonsmoker	47 (90.4)
Alcohol Use: (n=50)	
Yes	26 (52.0)
No	24 (48.0)

Global health status was based on women's perceived ratings of overall health and quality of life, physical functioning related to ability to perform everyday and strenuous activities, and fatigue was based on feelings of weakness and need to rest. Each scale was converted from a raw score to a score between 0 and 100. For global health status and physical functioning, a higher score indicated higher levels of quality of life and physical functioning, while a higher fatigue score indicated greater weakness and need to rest.

These markers were assessed at each of the three time points and divided into four quadrants: 0-25, 26-50, 51-75, and 76-100, to more easily determine changes throughout the enrollment period. Global health status greatly increased among women from initiation of radiation therapy to follow-up, with only 36% of women indicating a score between 76-100 at time point 1, but 63% of women indicating this score at time point 3 (Figure 2). Physical functioning, indicated in Figure 3, did not change greatly throughout the enrollment period, with a majority of women indicating a score of 76-100 at all three time periods (82%, 78%, and 90% of women, respectively). Changes in fatigue were seen throughout the period, although not as directly as in global health status (Figure 4). Fifty-four percent of women reported low levels of fatigue at initiation of radiation therapy, while 79% reported the same at follow-up six weeks after completion of therapy. Less than 10% of women reported high levels of fatigue, corresponding to a score of 51-100, at any given time point.

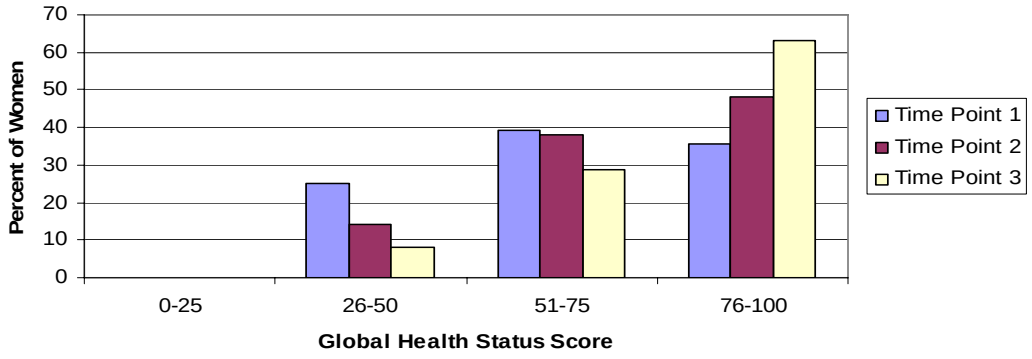
Quality of life was assessed for the prostate cancer patients using the RAND 36-Item Health Survey v2 (SF-36 v2) and UCLA Prostate Cancer Index questionnaire (Appendix C). Once again, three markers were used to assess quality of life at initiation of radiation therapy, completion of radiation therapy, and follow-up six weeks following therapy completion. General health was based on the patient's view of their personal health, their health related to others they know, and expectations of health changes in their future. Physical functioning related to ability to perform vigorous, moderate, and everyday activities, and vitality was based on the patient's energy level and feelings of weakness or fatigue. Raw scores were scaled to a final

score between 0 and 100, with a higher score indicating a higher quality of life. Each of the three markers were divided into the same four quadrants as with the breast cancer data to more easily determine changes in quality of life throughout the enrollment period.

There was a clear decrease in physical functioning among prostate cancer patients from initiation of radiation therapy to follow-up (Figure 5). Those reporting in the highest quadrant of scores, between 75 and 100, fell from 71% to 60% to 46% of men among the respective time points. Simultaneously, those reporting in the lowest quadrant between 0 and 25 rose from 8% to 27% to 39% of men. Vitality scores also decreased, especially between initiation and completion of radiation therapy, as seen in Figure 6. Thirty-nine percent of men reported high vitality scores at initiation of radiation therapy, which dropped to only 21% of men at completion of therapy. Finally, changes in general health throughout the enrollment period are shown in Figure 7. This marker was more varied than in the case of physical functioning and vitality; however, more men felt negatively, reporting scores between 0 and 25, about their general health at follow-up than at the initiation of radiation therapy. There was a slight increase, though, from 33% to 36%, in men reporting the highest scores between 75 and 100 from initiation of therapy to completion.

Relationship of supplement use to quality of life indicators were unable to be determined by the extent of this study and are currently under investigation.

Figure 2. Global Health Status Among Breast Cancer Patients



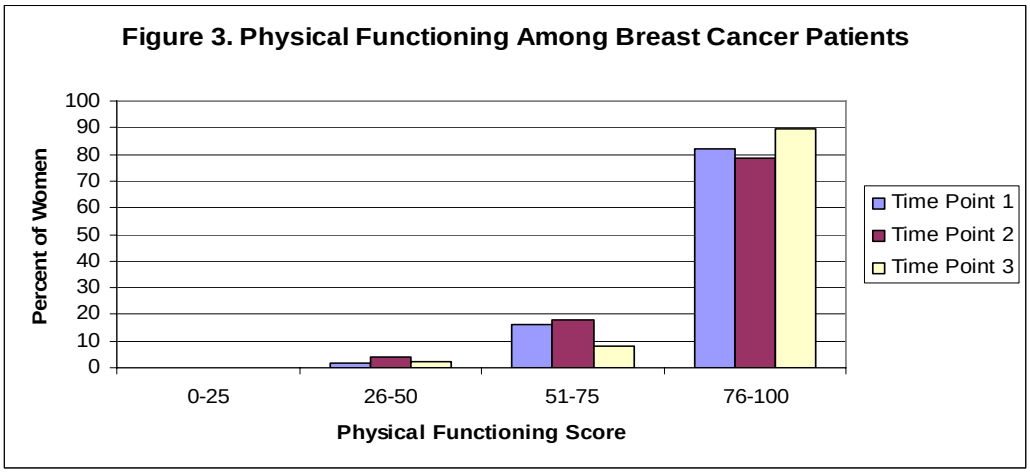


Figure 3. Physical Functioning Among Breast Cancer Patients
Percent of Women
100
90
80
70
60
50
40
30
20
10
0
0-25
26-50
51-75
76-100
Physical Functioning Score
Time Point 1
Time Point 2
Time Point 3

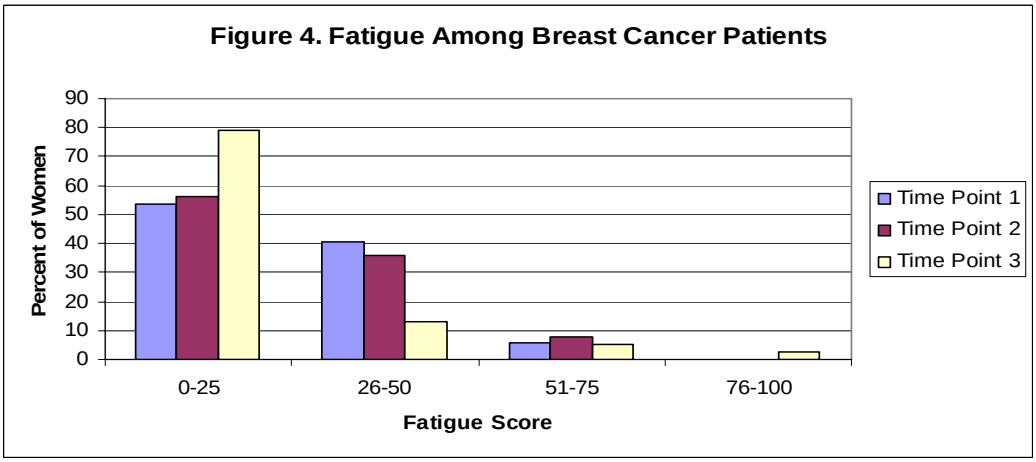


Figure 4. Fatigue Among Breast Cancer Patients
Percent of Women
90
80
70
60
50
40
30
20
10
0
0-25
26-50
51-75
76-100
Fatigue Score
Time Point 1
Time Point 2
Time Point 3

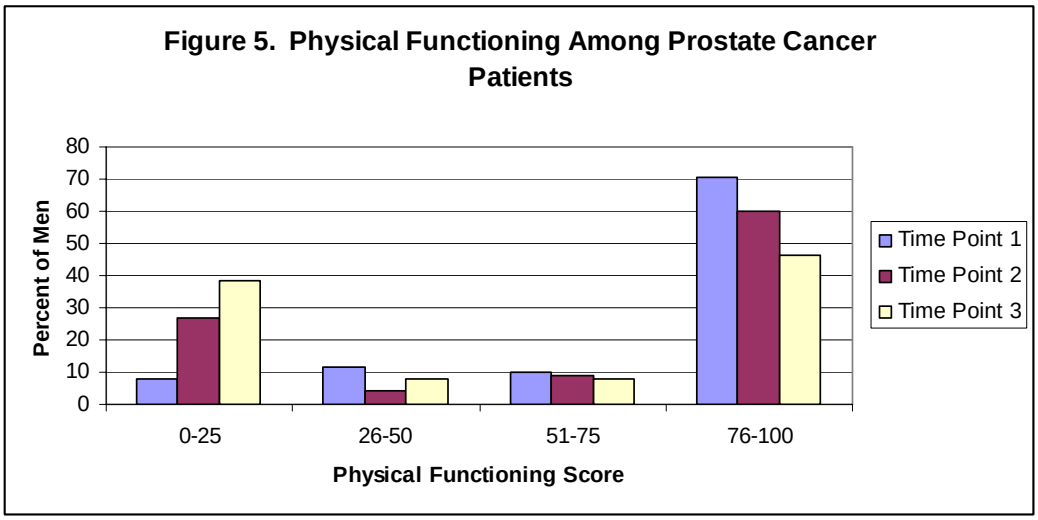
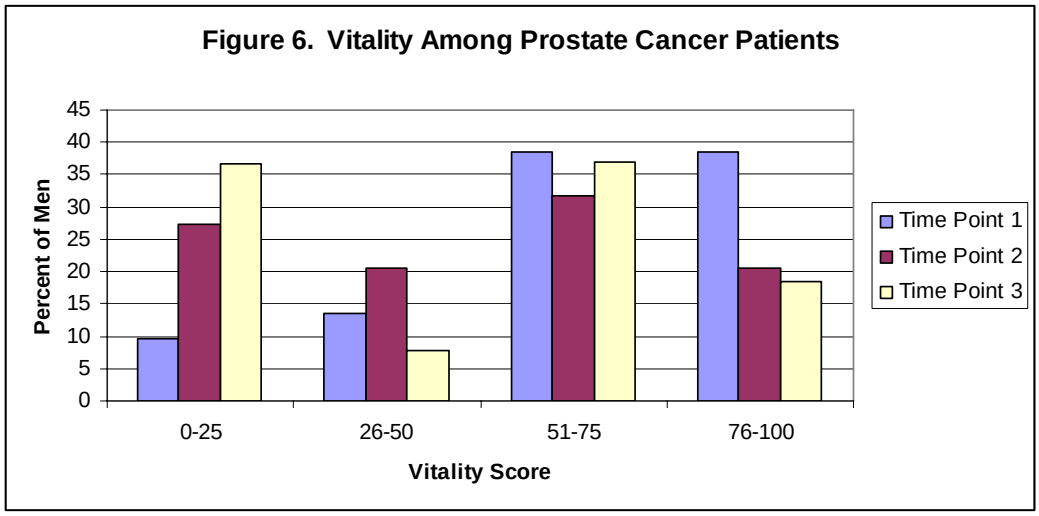
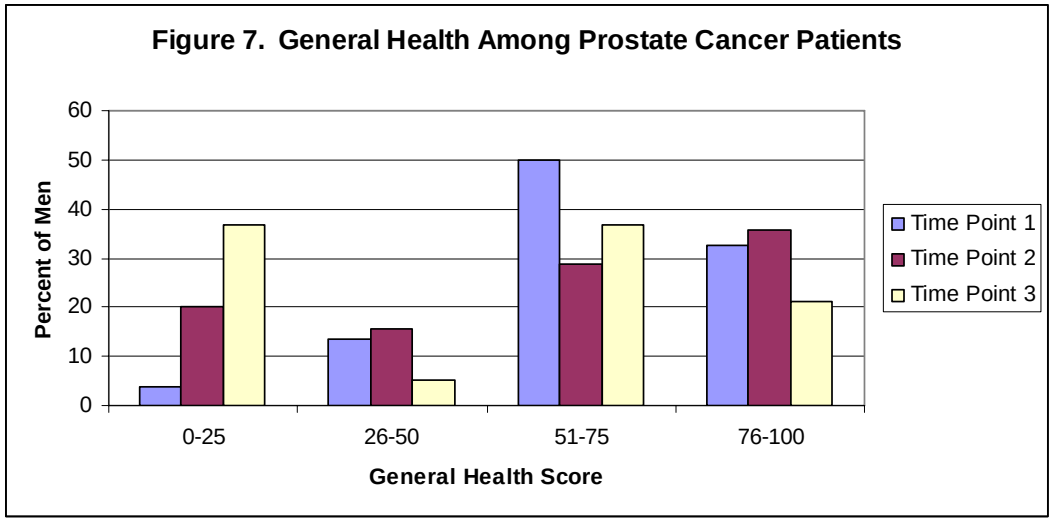


Figure 5. Physical Functioning Among Prostate Cancer Patients
Percent of Men
80
70
60
50
40
30
20
10
0
0-25
26-50
51-75
76-100
Physical Functioning Score
Time Point 1
Time Point 2
Time Point 3





Supplement Use Data:

Breast Cancer Patients:

At the initiation of radiation therapy, 73% (n=41) of women reported supplement use (Figure 8). A total of 133 different supplement products were consumed and an average of 3.2

supplements per woman were consumed among supplement users. Number of supplements consumed among breast cancer patients is seen in Figure 9. Fourteen women reported consumption of only one supplement, followed by 9 women reporting use of two supplements and 7 women reporting use of three supplements. The largest number of supplements consumed was 16, reported by one patient.

The most common supplement consumed was a combination multivitamin or multimineral (52%), followed by vitamin D and/or calcium products (32%), as shown in Figure 10. The two major antioxidant nutrients, vitamin C and vitamin E, were consumed by 15 women and 9 women, respectively. Forty-six percent of women reported consuming supplements containing these two antioxidant vitamins at the initiation of therapy, excluding those found in a multivitamin supplement. Herbal supplements, coenzyme Q10, and anti-arthritic supplements glucosamine and chondroitin were also reported among several women. Fourteen supplements which were consumed by only one woman were separated into a category noted as "other" (Table 3).

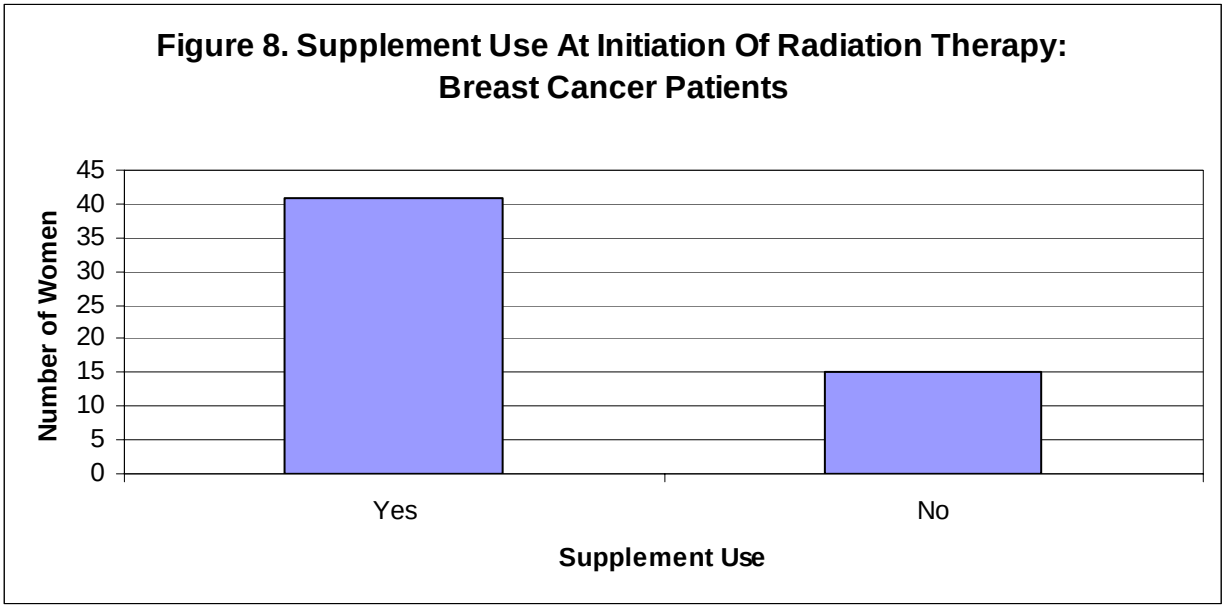


Figure 9. Number of Supplements Taken Among Supplement Users: Breast Cancer Patients

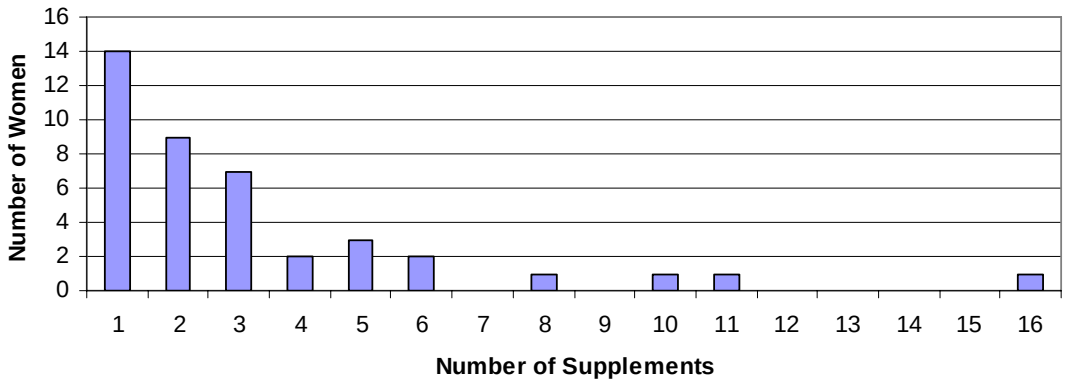


Figure 10. Categories of Dietary Supplements Consumed: Breast Cancer Patients

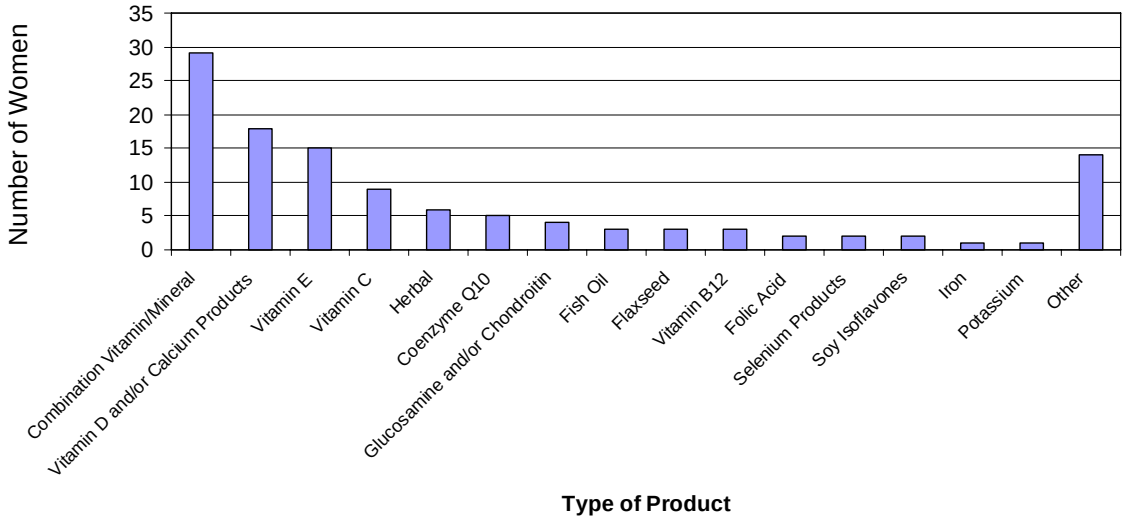


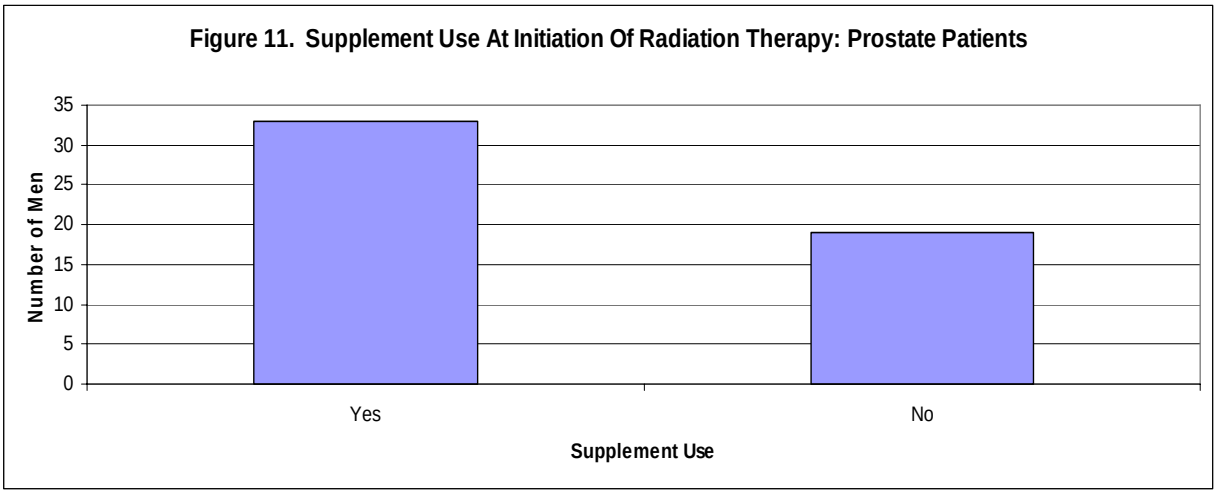
Table 3. Supplements classified as "other" among breast cancer patients.

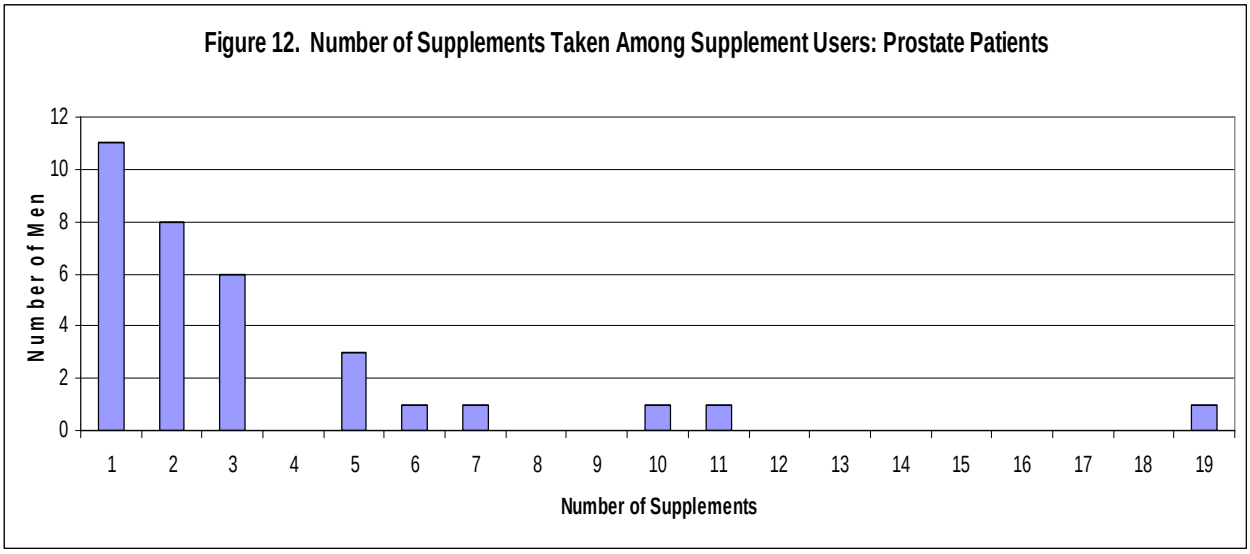
Conjugated linoleic acid	Mushroom Immune Def.
Wobenzyme	Protein bar
Sun Chlorella	Food Enzymes
Cranberry Extract	Trigger Immune
Bromelain	Whey protein
Cell Forte	Blood Build
Pancreatin	Juice Plus

Prostate Cancer Patients:

Among 52 prostate cancer patients enrolled in the study, 63% (n=33) reported consuming dietary supplements at the initiation of radiation therapy (Figure 11). A total of 113 different supplement products were consumed, and an average of 3.42 supplements were consumed among supplement users. Figure 12 illustrates the number of supplements taken among prostate cancer patients at initiation of radiation therapy. Twenty-five men reported taking between 1 and 3 supplements, with the most frequent being only a single supplement. One patient reported consuming 19 different supplement products.

As shown in Figure 13, the most common type of product consumed was a multivitamin or multimineral (44%), followed by single antioxidant nutrients vitamin E (27%) and vitamin C (19%), and vitamin D and/or calcium products (19%). Forty-six percent of men were consuming single antioxidant nutrient supplements at the initiation of radiation therapy. Herbal supplements were also fairly common among this cohort of patients, especially saw palmetto and garlic products, and were reported among 8 patients. Several unique supplements were consumed by this cohort and are noted as "other" in Table 4.





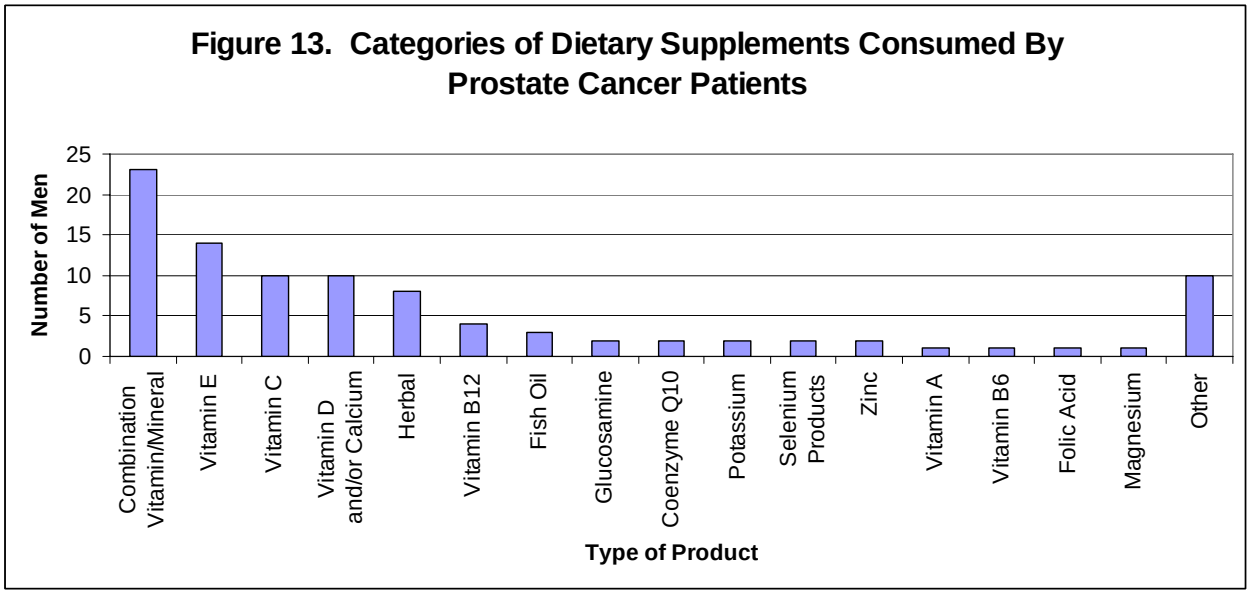


Table 4. Supplements classified as "other" among prostate cancer patients.

Juice Plus	Chlorella Super
Optiflora	Alpha Lipoin Acid
Flaxseed	Fiber Plan
Lysine	Colorad
Shark cartilage	Soy isoflavones

VI. Discussion

At initiation of radiation therapy, 73% of breast cancer patients and 63% of prostate cancer patients reported consumption of at least one dietary supplement. These percentages are significantly higher than averages for the general population, which have been reported at approximately 52% (Radimer, 2004). Furthermore, these percentages are higher than previously reported for cancer patients. In keeping with published literature, this study found that breast cancer patients and women are likely to take more supplements than individuals with other cancers or males (Patterson, 2003). In both cohorts, combination multivitamins and multiminerals were most common, but several other nutrients and supplement products were prevalent, specifically vitamin D and calcium products, vitamin C, vitamin E, and herbal products. An important finding of this study was that a significant number of breast and prostate cancer patients were consuming supplements with antioxidant nutrients at therapy initiation, which are now being investigated as having possible negative effects on radiation therapy. It is imperative that these patients become aware of the dosages of antioxidants they are consuming and the possible effects these products may have on their cancer treatment.

In addition to the findings involving supplement use among these populations, quality of life changed greatly between initiation of radiation and follow-up six weeks later. For breast cancer patients, global health status increased steadily throughout the period, while physical functioning and fatigue markers did not greatly change. These patients likely reported feelings of higher quality of life simply due to undergoing treatment and subsequent feelings of empowerment of their disease. Among prostate cancer patients, all three markers of quality of life assessed decreased from the beginning to the end of the enrollment period. This is to be expected, as radiation for prostate cancer often produces more severe side effects than in breast cancer. Moreover, greater difficulties in sexual function in men resulting from treatment

may cause the patients to overestimate feelings of ill health or low quality of life. In general, however, it is clear that treatment with radiotherapy affects several aspects of quality of life.

This study has several strengths and limitations. The most important strength of the study is its detail and accuracy in obtaining data about supplement use. Unlike many past studies, this analysis did not rely on self-report in that patients physically brought supplement bottles to their appointments rather than recall their names, dosages, and ingredients. This method will allow for much easier and more accurate quantification of data for future interventions in this population. However, it is important to realize that there are several confounding factors that may have contributed to these results. Health conditions other than cancer, possible chemotherapy or surgery before radiation, mental conditions, and personal beliefs likely played in a role in each patient's decision to begin or stop taking supplements. Quality of life data was rather subjective and changes in questionnaire answers could have been attributed to factors other than the radiation treatment. Finally, it is necessary to recognize that this study used a small, relatively homogeneous cohort of patients in an academic setting. The majority of participants were Caucasian, retired or employed with a steady income, and relatively well-educated, which are all indicators of increased supplement use. Therefore, the results and conclusions drawn may not be generalized to all breast and prostate cancer patients. More research is necessary to control for these factors and to more specifically quantify supplement use among a larger cohort of cancer patients.

VII. Significance

Completion of this project has set a foundation for future studies in the field of dietary supplements and cancer. Defining the supplement use of these two populations is a necessary step to begin a randomized clinical trial to investigate the effects of supplements on radiation therapy. Specifically, an ethical clinical trial should be designed to examine the effect of

antioxidant supplements on radiation, since a large proportion of these cohorts were consuming supplements with antioxidant nutrients at initiation of radiation therapy. Studies investigating the relationship between supplement use and quality of life may also be beneficial. In addition, understanding the trends in supplement usage among breast and prostate cancer patients will lead to more tailored educational interventions to both consumers and health professionals. Finally, future studies can use the existing data from the supplements taken among these populations to determine specific nutrient toxicities and deficiencies that may positively or negatively affect their therapy or cancer diagnosis.

VIII. Acknowledgments

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Finally, to my parents, who have always encouraged me to strive for academic and personal excellence, and who have been the voice of reason throughout this process. I owe much of my success to their love and support.

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APPENDIX A: DEMOGRAPHIC QUESTIONNAIRE

This brief questionnaire should take no more than 5 minutes to complete. You can choose to fill it in now and return it to the study coordinator immediately or return the questionnaire the next day before your scheduled radiation therapy.

Cancer Site:
- ☐ Prostate
- ☐ Breast

Date of Cancer Diagnosis: **_____ (month/ year)**

Age:
- ☐ ≤ 30 yr
- ☐ 31- 40 yr
- ☐ 41- 50 yr
- ☐ 51- 60 yr
- ☐ 61- 70 yr
- ☐ ≥70 yr

Gender:
- ☐ Male
- ☐ Female

Race/ Ethnicity:
- ☐ Caucasian
- ☐ African American
- ☐ Hispanic
- ☐ Others

Height: _____ m

Weight: _____ kg

Education Level:
- ☐ Nil Formal
- ☐ <High School
- ☐ High School
- ☐ College
- ☐ Graduate School

Employment:
- ☐ Paid
- ☐ Retired
- ☐ Unemployed
- ☐ Other

Mark the following therapies that you use NOW and have used BEFORE DIAGNOSIS, and indicate the number of times per week that you practice these therapies.

Now	Before Diagnosis
Do you practice any of the following?	
Psychological Therapies:	
☐ Relaxation Techniques Times per week: _____	☐ Relaxation Techniques Times per week: _____
☐ Imagery Times per week: _____	☐ Imagery Times per week: _____
☐ Biofeedback Times per week: _____	☐ Biofeedback Times per week: _____
☐ Hypnosis Times per week: _____	☐ Hypnosis Times per week: _____
☐ Self- Help Group Times per week: _____	☐ Self- Help Group Times per week: _____
Healing Therapies:	
☐ Acupuncture Times per week: _____	☐ Acupuncture Times per week: _____
☐ Aromatherapy Times per week: _____	☐ Aromatherapy Times per week: _____
☐ Chiropractic Care Times per week: _____	☐ Chiropractic Care Times per week: _____
☐ Energy Healing (e.g. Reiki) Times per week: _____	☐ Energy Healing (e.g. Reiki) Times per week: _____
☐ Homeopathy Times per week: _____	☐ Homeopathy Times per week: _____
☐ Massage Times per week: _____	☐ Massage Times per week: _____
☐ Naturopathy Times per week: _____	☐ Naturopathy Times per week: _____
☐ Yoga Times per week: _____	☐ Yoga Times per week: _____
☐ Lifestyle Diet What type of diet do you follow: ☐ "Heart Healthy" ☐ Vegetarian ☐ Low Carbohydrate- High Protein	☐ Lifestyle Diet What type of diet do you follow: ☐ "Heart Healthy" ☐ Vegetarian ☐ Low Carbohydrate- High Protein

☐ ☐ Macrobiotic ☐ “Weight Watchers” ☐ Other: _____	☐ ☐ Macrobiotic ☐ “Weight Watchers” ☐ Other: _____

APPENDIX B: EORTC QUALITY OF LIFE QUESTIONNAIRE-C30 AND EORTC QLQ-BR23

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the
number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will
remain strictly confidential.

Please fill in your initials: bbbb

Your birthdate (Day, Month, Year): cececdde

Today's date (Day, Month, Year): 31 cececdde

_

Not at A Quite Very
All Little a Bit Much

1. Do you have any trouble doing strenuous activities,
like carrying a heavy shopping bag or a suitcase? 1 2 3 4
2. Do you have any trouble taking a long walk? 1 2 3 4
3. Do you have any trouble taking a short walk outside of the house? 1 2 3 4
4. Do you need to stay in bed or a chair during the day? 1 2 3 4
5. Do you need help with eating, dressing, washing
yourself or using the toilet? 1 2 3 4

During the past week: Not at A Quite Very
All Little a Bit Much

6. Were you limited in doing either your work or other daily activities? 1 2 3 4
7. Were you limited in pursuing your hobbies or other
leisure time activities? 1 2 3 4
8. Were you short of breath? 1 2 3 4
9. Have you had pain? 1 2 3 4
10. Did you need to rest? 1 2 3 4
11. Have you had trouble sleeping? 1 2 3 4
12. Have you felt weak? 1 2 3 4
13. Have you lacked appetite? 1 2 3 4
14. Have you felt nauseated? 1 2 3 4
15. Have you vomited? 1 2 3 4
16. Have you been constipated? 1 2 3 4

Please go on to the next page

ENGLISH

During the past week: Not at A Quite Very
All Little a Bit Much

17. Have you had diarrhea? 1 2 3 4
18. Were you tired? 1 2 3 4
19. Did pain interfere with your daily activities? 1 2 3 4
20. Have you had difficulty in concentrating on things,
like reading a newspaper or watching television? 1 2 3 4
21. Did you feel tense? 1 2 3 4
22. Did you worry? 1 2 3 4
23. Did you feel irritable? 1 2 3 4
24. Did you feel depressed? 1 2 3 4
25. Have you had difficulty remembering things? 1 2 3 4
26. Has your physical condition or medical treatment
interfered with your family life? 1 2 3 4
27. Has your physical condition or medical treatment

interfered with your social activities? 1 2 3 4
28. Has your physical condition or medical treatment
caused you financial difficulties? 1 2 3 4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?
1 2 3 4 5 6 7
Very poor Excellent
30. How would you rate your overall quality of life during the past week?
1 2 3 4 5 6 7
Very poor Excellent

APPENDIX C: RAND 36-ITEM HEALTH SURVEY V2 (SF-36V2) AND UCLA PROSTATE CANCER INDEX

RAND 36-Item Health Survey v2 (SF-36 v2)

and

UCLA PROSTATE CANCER INDEX

Today's Date:

Month Day Year

The purpose of this questionnaire is to find out about your health in general and about how your prostate cancer and any treatment you received for it affects your quality of life.

Please read each question carefully before answering. If you are unsure about how to answer a question, please give the best answer you can. Remember that there are no right or wrong answers. If you have any questions, please call the research staff at .

Your answers to this questionnaire will be kept confidential and will be used only for research purposes. The information you give will be combined with the responses of other patients completing this questionnaire, and you will not be identifiable in any way.

Page 1 These first questions are about your <u>health in general</u>, BOTH RELATED and UNRELATED to your prostate cancer. We recognize that other diseases you may have in addition to your prostate cancer may affect your answers. Please give the best answer you can and remember there are no right or wrong answers.

. In general, would you say your health is:

1

Excellent.....1 (Circle one number.)

Very Good.....2

Good.....3

Fair.....4

Poor.....5

. COMPARED TO ONE YEAR AGO, how would you rate your health in general now?

2

Much better now than one year ago.....1 (Circle one number.)

Somewhat better now than one year ago.....2

About the same as one year ago.....3

Somewhat worse now than one year ago.....4

Much worse now than one year ago.....5

3. The following questions are about activities you might do during a typical day. <u>Does your health now limit you</u> in these activities? If so, how much?

(Circle 1, 2, or 3 on each line.)	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited at all**
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports.....	**1**	**2**	**3**
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	**1**	**2**	**3**
c. Lifting or carrying groceries.....	**1**	**2**	**3**
d. Climbing **several** flights of stairs.....	**1**	**2**	**3**
e. Climbing **one** flight of stairs.....	**1**	**2**	**3**
f. Bending, kneeling, or stooping.....	**1**	**2**	**3**
g. Walking **more than a**	**1**	**2**	**3**

mile.....			
h. Walking **several hundred yards**.....	**1**	**2**	**3**
i. Walking **one hundred yards**.....	**1**	**2**	**3**
j. Bathing or dressing yourself.....	**1**	**2**	**3**

Page 2

4. During the <u>PAST FOUR WEEKS</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

(Circle one number on each line.)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Cut down on the **amount of time** you spent on work or other activities.....	**1**	**2**	**3**	**4**	**5**
b. **Accomplished less** than you would like.....	**1**	**2**	**3**	**4**	**5**
c. Were limited in the **kind** of work or other activities.....	**1**	**2**	**3**	**4**	**5**
d. Had **difficulty** performing the work or other activities (for example, it took extra effort).....	**1**	**2**	**3**	**4**	**5**

5. During the <u>PAST FOUR WEEKS</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

(Circle one number on each line.)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the**	**None of the time**

					time
a. Cut down on the **amount of time** you spent on work or other activities.....	**1**	**2**	**3**	**4**	**5**
b. **Accomplished less** than you would like.....	**1**	**2**	**3**	**4**	**5**
c. Did work or other activities **less carefully than usual**.....	**1**	**2**	**3**	**4**	**5**

6. During the <u>PAST FOUR WEEKS</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all.....1 (circle one number.)
Slightly.....2
Moderately.....3
Quite a bit.....4
Extremely.....5

Page 3

. How much BODILY pain have you had during the <u>PAST FOUR WEEKS</u>?
7

None.....1 (circle one number.)
Very mild.....2
Mild.....3
Moderate.....4
Severe.....5
Very severe.....6

8. During the <u>PAST FOUR WEEKS</u>, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all.....1 (Circle one number.)
A little bit.....2
Moderately.....3

Quite a bit.....4

Extremely.....5

9. These questions are about how you feel and how things have been with you during the <u>PAST FOUR WEEKS</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>PAST FOUR WEEKS</u>...

(Circle one number on each line.)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?.....	**1**	**2**	**3**	**4**	**5**
b. Have you been very nervous?.....	**1**	**2**	**3**	**4**	**5**
c. Have you felt so down in the dumps that nothing could cheer you up?.....	**1**	**2**	**3**	**4**	**5**
d. Have you felt calm and peaceful?.....	**1**	**2**	**3**	**4**	**5**
e. Did you have a lot of energy?.....	**1**	**2**	**3**	**4**	**5**
f. Have you felt downhearted and depressed?	**1**	**2**	**3**	**4**	**5**
g. Did you feel worn out?.....	**1**	**2**	**3**	**4**	**5**
h. Have you been happy?.....	**1**	**2**	**3**	**4**	**5**
i. Did you feel tired?.....	**1**	**2**	**3**	**4**	**5**

Page 4

10. During the <u>PAST FOUR WEEKS</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time.....1 (Circle one number.)

Most of the time.....2

Some of the time.....3

A little of the time.....4

None of the time.....5

1. How TRUE or FALSE is <u>each</u> of the following statements for you?
1

(Circle one number on each line.)	**Definitely true**	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a. I seem to get sick a little easier than other people.....	**1**	**2**	**3**	**4**	**5**
b. I am as healthy as anyone I know	**1**	**2**	**3**	**4**	**5**
c. I expect my health to get worse..	**1**	**2**	**3**	**4**	**5**
d. My health is excellent.....	**1**	**2**	**3**	**4**	**5**

Please continue on next page.
Page 5

URINARY FUNCTION

This section is about your urinary habits. Please consider ONLY THE LAST 4 WEEKS.

2. Over the LAST 4 WEEKS, how often have you leaked urine?
1

Every day.....1 (Circle one number.)

About once a week.....2

Less than once a week.....3

Not at all.....4

13. Which of the following best describes your urinary control <u>during the</u>

<u>LAST 4 WEEKS</u>?

No control whatsoever.....1 (Circle one number.)

Frequent dribbling.....2

Occasional dribbling.....3

Total control.....4

14. How many pads or adult diapers per day did you usually use to control leakage <u>during the LAST 4 WEEKS</u>?

3 or more pads per day.....1 (Circle one number.)

1-2 pads per day.....2

No pads.....3

5. How big a problem, if any, has each of the following been for you?
1

(Circle one number on each line.)	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Dripping urine or wetting your pants?.....	0	1	2	3	4
b. Urine leakage interfering with your sexual activity?.....	0	1	2	3	4

Page 6

16. Overall, how big a problem has your urinary function been for you during the LAST 4 WEEKS?

No problem.....1 (Circle one number.)

Very small problem.....2

Small problem.....3

Moderate problem.....4

Big problem.....5

BOWEL HABITS

This section is about your bowel habits and abdominal pain. Please consider ONLY THE LAST 4 WEEKS.

17. How often have you had rectal urgency (felt like you had to pass stool, but did not) during the LAST 4 WEEKS?

More than once a day.....1 (Circle one number.)
About once a day.....2
More than once a week.....3
About once a week.....4
Rarely or never.....5

18. How often have you had stools (bowel movements) that were loose or liquid (no form, watery, mushy) during the LAST 4 WEEKS?

Never.....1 (Circle one number.)
Rarely.....2
About half the time.....3
Usually.....4
Always.....5

19. How much distress have your bowel movements caused you during the LAST 4 WEEKS?

Severe distress.....1 (Circle one number.)
Moderate distress.....2
A little distress.....3

No distress.....4

Page 7

20. How often have you had crampy pain in your abdomen or pelvis during the LAST 4 WEEKS?

Several times a day.....1 (Circle one number.)
About once a day.....2
Several times a week.....3
About once a week.....4
About once this month.....5
Rarely or never.....6

21. Overall, how big a problem have your bowel habits been for you during the LAST 4 WEEKS?

Big problem.....1 (Circle one number.)
Moderate problem.....2
Small problem.....3
Very small problem.....4
No problem.....5

SEXUAL FUNCTION

The next section is about your sexual function and sexual satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Remember that your answers to this questionnaire will be kept confidential and will be used only for research purposes. Please answer honestly about THE LAST 4 WEEKS ONLY.

2. How would you rate each of the following during the LAST 4 WEEKS?
2

(Circle one number on each line.)	Very Poor	Poor	Fair	Good	Very Good
a. Your level of sexual	1	2	3	4	5

desire?.....

b. Your ability to have an erection?.....	1	2	3	4	5
c. Your ability to reach orgasm (climax)?.....	1	2	3	4	5

3. How would you describe the usual QUALITY of your erections?

2

None at all.....1 (Circle one number.)

Not firm enough for any sexual activity.....2

Firm enough for masturbation and foreplay only.....3

Firm enough for intercourse.....4

Page 8

4. How would you describe the FREQUENCY of your erections?

2

I NEVER had an erection when I wanted one.....1 (Circle one number.)

I had an erection LESS THAN HALF the time I wanted one.....2

I had an erection ABOUT HALF the time I wanted one.....3

I had an erection MORE THAN HALF the time I wanted one.....4

I had an erection WHENEVER I wanted one.....5

---

5. How often have you awakened in the morning or night with an erection?

2

Never.....1 (Circle one number.)

Seldom (less than 25% of the time).....2

Not often (less than half the time).....3
Often (more than half the time).....4
Very often (more than 75% of the time).....5

---

6. During the LAST 4 WEEKS did you have vaginal or anal intercourse?

2

No.....1 (Circle one number.)
Yes, once.....2
Yes, more than once.....3

---

27. Overall, how would you rate your ability to function sexually during the LAST 4 WEEKS?

Very poor.....1 (Circle one number.)
Poor.....2
Fair.....3
Good.....4
Very good.....5

---

28. Overall, how big a problem has your sexual function been for you during the LAST 4 WEEKS?

No problem.....1 (Circle one number.)
Very small problem.....2
Small problem.....3
Moderate problem.....4
Big problem.....5

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DEMOGRAPHIC & BRIEF MEDICAL QUESTIONS

29. How old were you on your last birthday?

_____ (Enter age.)

30. How do you describe yourself?

White/Caucasian.....1 (Circle one number.)

Black/African-American.....2

Latino/Hispanic.....3

Asian/Pacific Islander.....4

Multi-Racial.....5

Other:

31. Which of the following best describes your current relationship?

Living with spouse or partner.....1 (Circle one number.)

In a significant relationship, but not living together.....2

Not in a significant relationship.....3

32. How much school did you complete?

Grade school or less.....1 (Circle one number.)

Some high school or technical school.....2

High school or technical school graduate.....3

Some college.....4

College Graduate.....5

Graduate or professional school after college...6

Please continue on next page.

Page 10

3. Have you ever had any of the following medical conditions?
3

(Please circle yes or no for every item.)	Yes	No
a. Diabetes …..…….	**1**	**0**
b. Heart attack, chest pain …….....	**1**	**0**
c. Stroke ……...	**1**	**0**
d. Amputation ……..	**1**	**0**
e. Circulation problems in your legs or feet .....….	**1**	**0**
f. Asthma, emphysema, breathing problems	**1**	**0**
g. Stomach ulcer, irritable bowel …….	**1**	**0**
h. Kidney disease …….....	**1**	**0**
I. Major depression …….	**1**	**0**
j. Seizures ……	**1**	**0**
k. Alcoholism or alcohol problems…….....	**1**	**0**
l. Drug problems……..…	**1**	**0**
m. Current or past cigarette smoker…...…….	**1**	**0**

34. Are you now working at a paying job?

Yes, full-time.....1 (Circle one number.)
Yes, part time.....2
No, but looking for a job.....3
No, retired.....4
No, disabled.....5

Comments:

Thank you very much for your time! Please remember to mail your completed questionnaire in the supplied envelope.

APPENDIX D: INTERNATIONAL REVIEW BOARD APPLICATION

INSTRUCTIONS FOR SUBMITTING PROTOCOLS FOR REVIEW BY

THE BIOMEDICAL SCIENCES INSTITUTIONAL REVIEW BOARD
THE OHIO STATE UNIVERSITY

Protocols received in the Office of Research Risks after the deadline date (first Monday of each month) will be scheduled for the following month's meeting. (Exception: The Monday deadline is moved to the Friday before Monday Holidays.) If all time slots are filled and a protocol is received on or before the deadline date, the protocol will be scheduled for the following month's meeting. Only protocols that are complete as defined below will be scheduled for review. Incomplete protocols will be returned to the principal investigator.

SUBMIT FIVE (5) SETS OF THE COMPLETE PROTOCOL **(Original + 4 copies) including:**

- **Summary Sheets**
- **Cover Page with original signatures**
- **Advertisement (if applicable)**
- **Consent form**
- **Research proposal**

IRB Administrative Assistant, Biomedical Sciences Human Subjects IRB
Office of Research Risks Protection
Room 300, Research Foundation Building
1960 Kenny Road
Campus

(Phone 292-9046)

1. **SUMMARY SHEETS with Cover Page**:

   a. Cover page (Form HS-029) must have original signatures of all principal and co-investigators and respective department chairs.

b. The abstract (overview of research) should be sufficiently informative to allow the reviewers a broad understanding of the research.

c. Do not use abbreviations for medical terminology.

d. Initial use of drug name should identify generic name in parentheses.

e. Complete each section - do not leave any question unanswered. Explain all reasonably expected risks.

2. **ADVERTISEMENT** should be limited to:

a. The name and address of the clinical investigator;

b. The purpose of the research and, in summary form, the eligibility criteria that will be used to admit subjects into the study;

c. A straightforward and truthful description of the benefit (e.g., payments or free treatment) to the subject from participation in the study; and

d. The location of the research and the person to contact for further information.

Note: No claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device.

3. **CONSENT FORM HS-028A (Rev. 7/93)**

   a. It is emphasized that the basic components and the language of the consent form cannot be altered. The consent form should be a single, continuous document of as many pages as necessary. The information should be written in language understandable to the subject. Explain medical terminology in LAYMEN'S LANGUAGE.

   b. Any payment and/or additional expenses to subject must be addressed in the consent form.

   c. If blood samples are to be drawn, state how many samples and the total volume in ounces. List standard risks: bruise at blood drawing site, discomfort or pain at the site, infection, fainting. If arterial stick, must also include artery damage with possible loss of circulation and gangrene.

   d. Include copies of all other standard procedure consent forms that pertain to the protocol; i.e., anesthesia, cardiac catheter, endoscopy, etc.

   e. For NO RISK protocols, waiver of written consent may be requested. Examples of activities that might be considered for waiver of written consent are surveys or questionnaires or other protocols involving no bodily invasion. (Venipuncture is considered minimal risk and must be accompanied by a consent form.)

4. **RESEARCH PROPOSAL** - (separate from the Summary Sheets; e.g., proposal that will be forwarded to an external funding agency, or as it will be presented for internal review process at the department or college level if the research activity is not to be supported by an external funding agency):

   a. Introductory background information that reviews information relevant to this research. This review should be sufficiently broad to serve as the justification for the conduct of this research. In the case of drug studies, complete information on the drug should be provided to the IRB. Also, in situations when this research is being done on humans for the first time, the results of all relevant studies on animals must be presented in the research proposal.

   b. Clearly stated objectives of the research.

   c. Design of the study.

   d. Methods employed in the collection and analysis of the data. Particular attention should be paid to justifying subjecting human beings to the risks of the research.

   e. Discussion of the significance of the research and impact on science or human welfare.

   f. Bibliography adequate to support the proposal statements.

   g. If the proposal has been submitted to other review committees (i.e., Medical Radionuclide Committee, Maternal-Fetal Committee, James Cancer Center Clinical Scientific Review Committee, etc.) attach all correspondence and relevant material from the respective committees. The investigator is responsible for obtaining approval from the various committees.

CATEGORIES OF RESEARCH ELIGIBLE FOR EXPEDITED

REVIEW BY HUMAN SUBJECTS REVIEW COMMITTEE

Research activities involving no more than **minimal risk** *and* in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed through the expedited review procedure:

☐ Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

☐ Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

☐ Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range; i.e., x-rays, microwaves.

☐ Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

☐ Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

☐ Voice recordings made for research purposes such as investigations of speech defects.

☐ Moderate exercise by healthy volunteers.

☐ The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

☐ Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

☐ Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

(For an EXPEDITED REVIEW check the appropriate box and return with the complete protocol.)

HS-029D (11/92)

THE OHIO STATE UNIVERSITY
BIOMEDICAL SCIENCES
INSTITUTIONAL REVIEW BOARD

Office Use:
Protocol No. _____
Date Received: _____

Protocols received in the Office of Research Risks Protection after the deadline date (first Monday of each month) will be scheduled for the following month's meeting. Exception: The deadline is moved to the Friday before Monday holidays If all time slots are filled and a protocol is received on or before the deadline date, the protocol will be scheduled for the following month's meeting. The IRB meets on the third Monday of each month). Only protocols that are complete will be scheduled for review. Incomplete protocols will be returned.

Principal Investigator: Steven K. Clinton, MD, Ph.D. _____

OSU Faculty or approved PI status **Typed Name** **Signature**

Academic Title: Associate Professor of Internal Medicine Phone No. 614.293.8396 Fax No. 614.293.7525

College: Medicine and Public Health Department/No. Internal Medicine/ 25256

Campus Address: A 434 Starling Loving Hall, 320 W. 10th Avenue

Co-Investigators: Elizabeth C. Miller, MS, RD _____
Typed Name **Signature**

Eileen C. Ang _____
Typed Name **Signature**

Protocol Title: XXX

Department Chair(s) Endorsement: Michael Caliguiri, MD _____

Typed Name **Signature**

Michael Grever, MD _____

Typed Name **Signature**

Proposed Research Involves:

YES **NO**

☐ ☐ Investigational Drug(s) or investigational use of marketed drugs(s). If yes, provide:
IND Number _____ Issued to _____ Generic Name: _____

☐ ☐ Investigational Devices(s). If yes, indicate NSR _____; or SR _____; if SR, provide: IDE Number _____; Issued to: _____.

☐ ☐ Radioactive Drugs or Unusual Exposure to External Radiation. Approval by the Medical Radionuclide Committee (Phone: 292-0122) is required prior to activation. Investigator is responsible for obtaining approval from both committees.

☐ ☐ Cancer-related Activities. Approval by the James Cancer Center Clinical Scientific Review Committee (Phone: 293-4976) is required prior to activation. Investigator is responsible for obtaining approval from both committees.

☐ ☐ Pregnant Women. Approval by Maternal-Fetal committee (Phone: 293-8736) is required prior to activation. Investigator is responsible for obtaining approval from both committees.

☐ ☐ Minors (Under 18 years of age)

☐ ☐ Cognitively Impaired

☐ ☐ Fetuses/In Vitro Fertilization

☐ ☐ Prisoners

BIOMEDICAL SCIENCES

SUMMARY SHEETS

ADDRESS EACH ITEM IN A COMPLETE AND CONCISE MANNER. (Do not leave any item blank with "See attached.) Use continuation pages when necessary.

1. Abstract (overview of research)

Background: The use of complementary and alternative medicine (CAM) has become significantly more prevalent over the past decade, and it may be more common among cancer patients. CAM are used for a variety of reasons such as; minimizing the effect of conventional treatment, enhancing quality of life or the desire to take control of health (Kao, 2000). The effects of CAM use during cancer treatment are largely unstudied, and it is possible that certain types of CAM, such as nutritional supplements and altermative medications, may impact the efficacy of radiation treatment. There are very few studies investigating the prevalence of CAM use among persons undergoing radiation treatment. This information is critical for future trials to investigate the effects of CAM therapies on cancer treatment, clinical outcomes, and quality of life.

Objective: Our objective is to quantify the use of CAM therapies in men with prostate cancer and women with breast cancer who are currently undergoing radiation therapy at The James Cancer Hospital and Solove Research Institute. We will collect information on the use of many different CAM therapies with an emphasis on nutritional supplement and alternative medication use. We will also determine if patients change their patterns of supplement and alternative medication use during or after radiation treatment and we will use a reliable and valid questionnaire to measure quality of life.

Design: This study will consist of a brief interview and a take-home questionnaire at three different time points for a total of 50 men with prostate cancer and 50 women with breast cancer who are scheduled to begin radiation therapy at The James Cancer Hospital and Solove Research Institute. We will ask all eligible patients to answer a few questions and to bring their supplement bottles to the clinic where we will photocopy the labels for our records. Descriptive statistics will be completed to provide information on the frequency of different types of CAM therapies and associations between specific CAM therapies and demographic characteristics and quality of life.

2. Describe the requirements for a subject population and explain the rationale for using in this population

special groups such as prisoners, children, the mentally disabled or groups whose ability to give voluntary

informed consent may be in question. Address means of pregnancy screening for females.

None of the special groups above will be enrolled in this study.
Pregnant women will not be enrolled in this study.

The requirements include the following; study participants must:

- Be currently scheduled to undergo external beam radiation therapy or brachytherapy at The James Cancer Hospital and Solove Research Institute for primary treatment for newly diagnosed prostate or breast cancer.
- Not have known metastatic disease.

3. Describe and assess any potential risks - physical, psychological, social, legal, financial, or other - and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

There are no significant risks involved with participating in this study. Eligible patients who do not wish to disclose their use of nutritional supplements will not be included in the study.

4. Describe consent procedures to be followed, including how and where informed consent will be obtained. (The use of a finder's fee for recruiting subjects is not permitted.)

All patients will undergo an informed consent process. The study coordinator will call eligible patients prior to the initiation of radiation therapy and will describe the purpose of the survey. Patients will be informed that there is no risk to them and no additional visits to the clinic are required for the purposes of this study. Patients who do not wish to participate will not be included in the study. Patients will be asked to sign the informed consent form during their simulation visit, before the initiation of radiation therapy.

BIOMEDICAL SCIENCES

SUMMARY SHEETS

ADDRESS EACH ITEM IN A COMPLETE AND CONCISE MANNER. (Do not leave any item blank with "See attached.) Use continuation pages when necessary.

5. Describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks and an assessment of their likely effectiveness.

We will review each patients medical chart to obtain demographic information. This information in addition to the study documents will be kept in a locked filing cabinet in Starling Loving Hall and only persons directly involved in the study (Steven K. Clinton, Elizabeth Miller and Eileen Ang) will have access to the study files.

The study poses no obvious risk to the patient.

Patient names will not be used in any publication resulting from this study.

6. Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.

The individual subject may not benefit from this study. There is no obvious risk of this study because it is simply a collection of information at three different time points, consisting of a brief interview and a take-home questionnaire.

The benefits to the society may be large. This study will describe nutritional supplement and alternative medicine use in men with prostate cancer and women with breast cancer who are undergoing radiation therapy and to determine the association between supplement usage patterns with demographic characteristics and reported quality of life. This information will be useful for future trials to investigate the effects of CAM therapies on cancer treatment, clinical outcomes and quality of life.

7. Compare the risks versus the benefits.

The risk to the patient is minimal while the potential benefits to our society are large.

8. Will the subjects for the study be paid for participating in this study? Yes No X
If yes, how much?

Will subjects be paid for selected activities (e.g., blood drawing) or for general participation in the study?

***NOTE:** **All information concerning payments, including the amount and schedule of payment, must be included in the consent form.**

Is there any other inducement? Yes No X If so, please describe.

9. Will advertising be used to recruit subjects? Yes No X If yes, attach a copy of the proposed advertisement.

SOURCE OF FUNDING FOR PROPOSED RESEARCH: (Check A or B)

A. OSURF: Sponsor _____ RF Proposal/Project No. _____

B. Other (Identify) _____

Information about the funding/sponsorship of human subjects research activities is required for administrative purposes. Such information is generally not required as part of the human subjects review process.

HS-029C (Rev. 7/93)

CONSENT TO INVESTIGATIONAL TREATMENT OR PROCEDURE

I, _____, hereby authorize or direct Steven K. Clinton, MD, Ph.D., **associates or assistants of his/her choosing, to perform the following treatment or procedure (describe in general terms),**

To ask me questions about my use of nutritional supplements (vitamins, minerals, herbs, botanicals, etc.) and for me to fill in a questionnaire on quality of life and alternative therapies I use.

To allow the investigators to photocopy ingredient content of supplement consumed.

Examples of questions that I may be asked include questions about the dose, formulation, brand name, and the number of years I have taken a specific nutritional supplement, the types and frequency of alternative therapies I use and general quality of life questions. These questions should take no more than ten (10) minutes to answer.

upon _____.
(myself or name of subject)

The experimental (research) portion of the treatment or procedure is:

Approximately 50 men and 50 women will be enrolled in this study.

If I decide to participate in this study, I will answer a brief questionnaire about my use of Complementary and Alternative Medicine practices and a quality of life questionnaire. In addition I will bring in the bottles of all of the nutritional supplements and alternative medications I currently use to be photocopied by the study coordinator.

This process will be repeated three times over the course of approximately two to three months: at the beginning of radiation treatment, at the end of radiation treatment, and at my first follow up appointment.

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

I will not be paid for my participation in this study, nor will this study result in any extra cost to me.

This is done as part of an investigation entitled:
XXX

1. **Purpose of the procedure or treatment:**

   To evaluate the use of complementary and alternative medicine practices among men with prostate cancer and women with breast cancer who are currently undergoing radiation therapy at The James Cancer Hospital and Solove Research Institute.

   To determine if the use of complementary and alternative medicine is related to quality of life in breast cancer and prostate cancer patients undergoing radiation therapy.

2. **Possible appropriate alternative procedure or treatment (not to participate in the study is always an option):**

   I may choose not to participate without affecting my current or future medical care.

3. Discomforts and risks reasonably to be expected:

There are no risks associated with participation in this study.

4. Possible benefits for subjects/society:

I may not benefit in any way from this study, nor is there any risk to me.

The possible benefits to society include a better understanding of complementary and alternative medicine use in men with prostate cancer or women with breast cancer who are undergoing radiation therapy.

5. Anticipated duration of subject's participation (including number of visits):

This study consists of a brief interview during my regularly scheduled appointment and a take home questionnaire.

No additional visits to the clinic are required for this study.

I hereby acknowledge that _____ has provided information about the procedure described above, about my rights as a subject, and he/she answered all questions to my satisfaction. I understand that I may contact him/her at Phone No. 614.293.8396 **should I have additional questions. He/She has explained the risks described above and I understand them; he/she has also offered to explain all possible risks or complications.**

I understand that, where appropriate, the U.S. Food and Drug Administration may inspect records pertaining to this study. I understand further that records obtained during my participation in this study that may contain my name or other personal identifiers may be made available to the sponsor of this study. Beyond this, I understand that my participation will remain confidential.

I understand that I am free to withdraw my consent and participation in this project at any time after notifying the project director without prejudicing future care. No guarantee has been given to me concerning this treatment or procedure.

I understand in signing this form that, beyond giving consent, I am not waiving any legal rights that I might otherwise have, and I am not releasing the investigator, the sponsor, the institution, or its agents from any legal liability for damages that they might otherwise have.

In the event of injury resulting from participation in this study, I also understand that immediate medical treatment is available at University Hospitals of The Ohio State University and that the costs of such treatment will be at my expense; financial compensation beyond that required by law is not available. Questions about this should be directed to the Office of Research Risks at 292-5958.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

AM

Date: _____ **Time** _____ *PM* **Signed** _____

(Subject)

Witness (es) if required _____ _____

(Person Authorized to Consent for Subject if Required)

_____

I certify that I have personally completed all blanks in this form and explained them to the subject or his/her representative before requesting the subject or his/her representative to sign it.

Date: _____ **Signed** _____

(Signature of Project Director or his/her Authorized Representative)

HS-028A (Rev. 7/93)

THE OHIO STATE UNIVERSITY
BIOMEDICAL SCIENCES
HUMAN SUBJECTS REVIEW COMMITTEE

C H E C K L I S T * FOR PRINCIPAL INVESTIGATOR'S USE - DO NOT RETURN

___1. Are there five (5) copies of the complete protocol? (A complete protocol consists of four major components - Biomedical Summary Sheets, Advertisement, Consent Form and Research Proposal.)

BIOMEDICAL SUMMARY SHEETS

___2. Have all (original) signatures of the investigators and department chairs been obtained? (When more than one department is involved, the signature of each chair must be obtained.)

___3. Are the summary sheets written in sufficient detail and lay terminology to all the committee to make an informed decision?

___4. Are all items filled-in? (Continuation pages are allowed when there is insufficient space for entire response. Do not leave blank or indicate "See Attached".)

___5. If the summary sheets have been re-typed, has the wording of Items 1 through 9 been re-typed to correspond with the response?

___6. Has the Investigational Drug Number (IND) or Investigational Device Number (IDE) been included?

CONSENT FORM (Rev. 11/92)

___7. Is the standard wording of the consent form in bold type or highlighted in such a way that it stands out from the fill-in portions?

___8. Is the consent form written in language easily understood by a lay person; and, with enough detail to inform subjects exactly what will be expected of them?

___9. If the study is a double blind and/or randomized study, is it explained in lay language?

___10. Are all abbreviations spelled out?

___11. If females are to participate in the study, has it been clarified as to whether they may be pregnant, or what means will be used to document such?

___12. If blood is to be drawn, has the amount been stated in ounces and the number of samples indicated?

___13. Have the risks of blood drawing been specified? (Bruise at blood drawing site, discomfort or pain at the site, infection, fainting.)

___14. If subjects will incur any expenses as a result of participating in the study, have these expenses been specified with regard to who will be responsible for payment; i.e., subject, insurance, Medicare, etc?

___15. Are subjects being paid for participation? If so, has it been shown?

RESEARCH PROPOSAL

___ 1. In the case of drug studies, has complete information on the drug been included?

___ 2. Has a bibliography been included?

HS-029F (7/93)

APPENDIX E: CONSENT FORMS

CONSENT TO INVESTIGATIONAL TREATMENT OR PROCEDURE

I, _____, hereby authorize or direct Steven K. Clinton, MD, Ph.D., **associates or assistants of his/her choosing, to perform the following treatment or procedure (describe in general terms),**

To ask me questions about my use of nutritional supplements (vitamins, minerals, herbs, botanicals, etc.) and for me to fill in a questionnaire on quality of life and alternative therapies I use.

To allow the investigators to photocopy ingredient content of supplement consumed.

Examples of questions that I may be asked include questions about the dose, formulation, brand name, and the number of years I have taken a specific nutritional supplement, the types and frequency of alternative therapies I use and general quality of life questions. These questions should take no more than ten (10) minutes to answer.

upon _____.
(myself or name of subject)

The experimental (research) portion of the treatment or procedure is:

Approximately 60 men and 60 women will be enrolled in this study.

If I decide to participate in this study, I will answer a brief questionnaire about my use of Complementary and Alternative Medicine practices and a quality of life questionnaire. In addition I will bring in the bottles of all of the nutritional supplements and alternative medications I currently use to be photocopied by the study coordinator.

This process will be repeated three times over the course of approximately two to three months:
For radiation therapy patients: at the beginning of radiation treatment, at the end of radiation treatment, and at my first follow up appointment.
For brachytherapy patients: before brachytherapy, 5 weeks after brachytherapy and 11 weeks after brachytherapy during their clinical visits with Dr. Clinton.

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

I will not be paid for my participation in this study, nor will this study result in any extra cost to me.

This is done as part of an investigation entitled:

Use of nutritional supplements and CAM (complementary and alternative medicine) by prostate and breast cancer patients undergoing radiotherapy

1. Purpose of the procedure or treatment:

To evaluate the use of complementary and alternative medicine practices among men with prostate cancer and women with breast cancer who are currently undergoing radiation therapy at The James Cancer Hospital and Solove Research Institute.

To determine if the use of complementary and alternative medicine is related to quality of life in breast cancer and prostate cancer patients undergoing radiation therapy.

2. Possible appropriate alternative procedure or treatment (not to participate in the study is always an option):

I may choose not to participate without affecting my current or future medical care.

3. Discomforts and risks reasonably to be expected:

There are no risks associated with participation in this study.

4. Possible benefits for subjects/society:

I may not benefit in any way from this study, nor is there any risk to me.

The possible benefits to society include a better understanding of complementary and alternative medicine use in men with prostate cancer or women with breast cancer who are undergoing radiation therapy.

5. Anticipated duration of subject's participation (including number of visits):

This study consists of a brief interview during my regularly scheduled appointment and a take home questionnaire.

No additional visits to the clinic are required for this study.

I hereby acknowledge that _____ has provided information about the procedure described above, about my rights as a subject, and he/she answered all questions to my satisfaction. I understand that I may contact him/her at Phone No. 614.293.8396 **should I have additional questions. He/She has explained the risks described above and I understand them; he/she has also offered to explain all possible risks or complications.**

I understand that, where appropriate, the U.S. Food and Drug Administration may inspect records pertaining to this study. I understand further that records obtained during my participation in this study that may contain my name or other personal identifiers may be made available to the sponsor of this study. Beyond this, I understand that my participation will remain confidential.

I understand that I am free to withdraw my consent and participation in this project at any time after notifying the project director without prejudicing future care. No guarantee has been given to me concerning this treatment or procedure.

I understand in signing this form that, beyond giving consent, I am not waiving any legal rights that I might otherwise have, and I am not releasing the investigator, the sponsor, the institution, or its agents from any legal liability for damages that they might otherwise have.

In the event of injury resulting from participation in this study, I also understand that immediate medical treatment is available at University Hospitals of The Ohio State University and that the costs of such treatment will be at my expense; financial compensation beyond that required by law is not available. Questions about this should be directed to the Office of Research Risks at 292-5958.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

AM

Date: _____ **Time** _____ *PM* **Signed** _____

(Subject)

Witness (es) if required _____ _____

(Person Authorized to Consent for Subject if Required)

_____

I certify that I have personally completed all blanks in this form and explained them to the subject or his/her representative before requesting the subject or his/her representative to sign it.

Date: _____ **Signed** _____

(Signature of Project Director or his/her Authorized Representative)

HS-028A (Rev. 7/93)

APPENDIX F: HIPAA FORMS

THE OHIO STATE UNIVERSITY
HIPAA RESEARCH AUTHORIZATION FORM

Beginning April 14, 2003, the new HIPAA Privacy Rule requires that Ohio State University Principal Investigators (PIs) provide research subjects with greater detail than what is currently included in the IRB-approved consent form concerning how a subject's past, present and future health-related information (collectively, Protected Health Information or PHI) will be used, shared and protected during the research. Specifically, the Privacy Rule now requires that PIs inform subjects of the following: 1) what specific kinds of information will be used or disclosed to others during the course of the research; 2) the specific identities of collaborating investigators, sponsor companies or sponsor agencies that will potentially receive copies of subjects' PHI during the research; 3) that subjects have a right to review their research-related PHI; and 4) that subjects have the express right to revoke their authorizations for the release of PHI at any time.

To meet these new requirements, PIs using PHI obtained from medical or research records from the Ohio State University Hospitals, The Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, OSU & Harding Behavioral Health Care & Medicine, the Ohio State University Hospitals East and the Primary Care Network (the University Health System), or other University operated health centers or clinics, must now complete and receive a signed copy of the University's "Authorization to Use Personal Health Information in Research" form (the Authorization) below from subjects enrolling in research studies on or after April 14th (or be granted a waiver by a HIPAA Privacy Board) in addition to obtaining a signed IRB-approved consent form. The form will need to be carefully prepared by PIs to ensure that the Authorization covers ALL of the necessary uses and disclosures of personal health information used in clinical research. Failure to do so may violate the Privacy Rule and result in penalties against the University as well as individual civil and criminal penalties against the Principal Investigator.

INSTRUCTIONS TO RESEARCHERS
FOR PREPARING THE RESEARCH AUTHORIZATION FORM

1. Complete the first section of the Authorization form with title of the study, the OSU IRB protocol number, and PI name. Add subject name at the time of authorization. Do not include these instructions as part of the completed Authorization form.

2. "Uses and Disclosures Covered by this Authorization" – List every known non-OSU person, class of persons, or organizations (including the sponsor agency or company, known subsidiaries of the sponsor, cooperative data groups, etc.) that may create, disclose, receive, and/or use the information in connection with the study. Fill in the blanks on the form (and delete the instructions in italics as well as inapplicable bulleted sections) as appropriate. If information will not be disclosed outside of The Ohio State University, delete all bullets and insert "None". Note: if a person(s) or organization is not listed on the form, they may not create, disclose, receive or use PHI in connection with the study.

3a. "HIPAA Privacy Contact" – If the research involves the use of medical records from the University Health System, where applicable, insert the name and address of Margaret Johnson, HIPAA Privacy Manager, the Ohio State University Medical Center, 140 Doan Hall, 410 W. Tenth Avenue, Columbus, Ohio 43210.

3b. If the research solely involves the use of personal health records at non-University Health System clinics or health care facilities (for example, the Dental School, Optometry School, Nisonger Center, Younkin Center, Psychological Services Center, Anxiety and Stress Disorder Clinic, Marriage & Family Therapy Clinic, Camera Center or faculty practice group such as OSU-P) insert the name and address of the appropriate Privacy Contact for the center, school, clinic or practice group. If unknown, contact the director of the health center, school, clinic or practice group or the Office of Legal Affairs at (614) 292-0611 for the name and address of the applicable Privacy Contact.

4. The Authorization must be presented to all newly enrolled or "re-consented" subjects in IRB-approved research beginning April 14, 2003 at the time the IRB-approved consent form is signed. The subject or his/her legally authorized representative must be provided with a copy of this form after it has been signed. The original, signed copy must be retained in the research file for a period of six years from the date the Authorization was signed (or longer, according to sponsor requirements). Prior IRB approval of the Authorization is not required; however, the Privacy Contact and/or HIPAA Privacy Board may conduct audits of the Authorization to ensure completeness.

5a. "Notice of Privacy Practices" – Each subject who receives health care services at the University on or after April 14, 2003 should receive a copy of a Notice of Privacy Practices (NPP) and sign an acknowledgement (NPP Acknowledgement form) that (s)he obtained the NPP.

5b. If the research involves the use of health and/or medical records from the University Health System and the subject has not received a copy of the University Health System's NPP, provide the subject with a copy of the NPP. The subject should sign a copy of the University Health System's NPP Acknowledgement form. The original, signed copy of the NPP Acknowledgement form must be retained in the research file for a period of six years from the date the NPP Acknowledgement was signed (or longer, according to sponsor requirements). The University Health System's NPP and NPP Acknowledgement form are available in electronic format on the Office of Responsible Research Practices (ORRP) website at http://www.orrp.ohio-state.edu/ as well as the Medical Center's website at http://www.osumedcenter.edu.

5c. If the research involves the use of health records at other non-University Health System clinics or facilities (including the sites listed above in item 3b.) and the subject has not received a copy of the facility or clinic's individual NPP, provide the subject with a copy of the NPP. Contact the director of the applicable health center, school, clinic or practice group to obtain a copy of the NPP and the NPP Acknowledgement form. The original, signed copy of the NPP Acknowledgement form must be retained in the research file for a period of six years from the date the NPP Acknowledgement was signed (or longer, according to sponsor requirements).

THE OHIO STATE UNIVERSITY

AUTHORIZATION TO USE

PERSONAL HEALTH INFORMATION IN RESEARCH

Title of the Study: Use of Nutritional Supplements and CAM (Complementary and Alternative Medicine) by Prostate and Breast Cancer Patients Undergoing Radiotherapy.

OSU Protocol Number: 2002C0263

Principal Investigator: Steven K. Clinton, MD. Ph.D.

Subject Name_____

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University's Notice of Privacy Practices or the study before signing this form.

Initials/Date: _____

Those Who May Use, Share And Receive Your Information As Part Of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.
- Those who oversee the study will have access to your information, including:
    - Members and staff of the Ohio State University's Institutional Review Boards, including the Western Institutional Review Board
    - The Office for Responsible Research Practices
    - University data safety monitoring committees
    - The Ohio State University Research Foundation
- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
    - The Food and Drug Administration
    - The Office for Human Research Protections
    - The National Institutes of Health
    - The Ohio Department of Human Services

These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study: Not applicable

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Initials/Date_____

Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.-
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:

  Steven K. Clinton MD. Ph.D. at A434 Starling Loving Hall, 320 West 10th Avenue, Columbus, OH 43210-1240.

  or call the HIPAA privacy officer at 614.293.4477.
- Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

- If you have any questions relating to your privacy rights, please contact the HIPAA privacy officer at 614.293 4477.
- If you have any questions relating to the research, please contact Steven K. Clinton MD. Ph.D. at 614 293 8396.

Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Steven K. Clinton MD. Ph.D. and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature_____
(Subject or Legally Authorized Representative)

Name _____
(Print name above)
(If legal representative, also print relationship to subject.)

Date_____ Time _____ AM / PM